

EXHIBIT K



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Chinese Chemicals Flow Unchecked to Market

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MILAN — In January, Honor International Pharmtech was accused of shipping counterfeit drugs into the United States. Even so, the Chinese chemical company — whose motto is “Thinking Much of Honor” — was openly marketing its products in October to thousands of buyers here at the world’s biggest trade show for pharmaceutical ingredients.

Other Chinese chemical companies made the journey to the annual show as well, including one manufacturer recently accused by American authorities of supplying steroids to illegal underground labs and another whose representative was arrested at the 2006 trade show for patent violations. Also attending were two exporters owned by China’s government that had sold poison mislabeled as a drug ingredient, which killed nearly 200 people and injured countless others in Haiti and in Panama.

Yet another chemical company, Orient Pacific International, reserved an exhibition booth in Milan, but its owner, Kevin Xu, could not attend. He was in a Houston jail on charges of selling counterfeit medicine for schizophrenia, prostate cancer, blood clots and Alzheimer’s disease, among other maladies.

While these companies hardly represent all of the nearly 500 Chinese exhibitors, more than from any other country, they do point to a deeper problem: Pharmaceutical ingredients exported from China are often made by chemical companies that are neither certified nor inspected by Chinese drug regulators, The New York Times has found.

Because the chemical companies are not required to meet even minimal drug-manufacturing standards, there is little to stop them from exporting unapproved, adulterated or counterfeit ingredients. The substandard formulations made from those ingredients often end up in pharmacies in developing countries and for sale on the Internet, where more Americans are turning for cheap medicine.

In Milan, The Times identified at least 82 Chinese chemical companies that said they made and exported pharmaceutical ingredients — yet not one was certified by the State Food and Drug Administration in China, records show. Nonetheless, the companies were negotiating deals at the pharmaceutical show, where suppliers wooed customers with live music, wine and vibrating chairs.

One of them was the Wuxi Hexia Chemical Company. When The Times showed Yan Jiangying, a top Chinese drug regulator, a list of 186 products being advertised by the company, including active pharmaceutical ingredients and finished drugs, Ms. Yan said, “This is definitely against the law.”

Yet in China, chemical manufacturers that sell drug ingredients fall into a regulatory hole. Pharmaceutical companies are regulated by the food and drug agency. Chemical companies that make products as varied as fertilizer and industrial solvents are overseen by other agencies. The problem arises when chemical companies cross over into drug ingredients. “We have never investigated a chemical company,” said Ms. Yan, deputy director of policy and regulation at the State Food and Drug Administration. “We don’t have jurisdiction.”

China’s health officials have known of this regulatory gap since at least the mid-1990s, when a chemical company sold a tainted ingredient that killed nearly 100 children in Haiti. But Chinese regulatory agencies have failed to cooperate to stop chemical companies from exporting drug products.

In 2006, at least 138 Panamanians died or were disabled after another Chinese chemical company sold the same poisonous ingredient, diethylene glycol, which was mixed into cold medicine.

China has an estimated 80,000 chemical companies, and the United States Food and Drug Administration does not know how many sell ingredients used in drugs consumed by Americans.

The Times examined thousands of companies selling products on major business-to-business Internet trading sites and found more than 1,300 chemical companies offering pharmaceutical ingredients. How many others sell drug ingredients but don’t advertise this way on the Web is not known.

If the Milan show is any guide, most, if not all, are not certified by China’s drug authorities.

China exports drug ingredients to customers in 150 countries, said Sun Dongliang, a Chinese

trade official who helped organize his country's Milan exhibitors. Many suppliers have passed inspections by drug authorities and sell active pharmaceutical ingredients, or A.P.I.'s, of high quality, buyers say.

"Sometimes you can just have your lunch on the floor of the factory because it's so clean and so perfect, sometimes much better than in Europe," said Jean-François Quarre, a French drug company official who had a booth in Milan. But Mr. Quarre cautioned that he has seen the other side as well. "It's frightening."

At their worst, uncertified chemical companies contribute to China's notoriety as the world's biggest supplier of counterfeit drugs, which include unauthorized copies as well as substandard, even harmful, formulations. "Underregulated manufacturers are increasingly becoming the source of A.P.I.'s used in the production of counterfeit medicine," R. John Theriault, until recently Pfizer's head of global security, said in a statement to Congress.

Because United States drug regulators require pharmaceutical suppliers to meet high standards, the American supply chain is among the world's safest. But as China's chemical suppliers multiply, Congressional investigators are questioning the F.D.A.'s ability to protect consumers.

Even some Chinese chemical companies recognize their limitations in making pharmaceuticals.

"We don't have the resources and means to produce medicine," said Gu Jinfeng, a salesman for Changzhou Watson Fine Chemical. "The bar for producing chemicals is pretty low."

Even so, Watson Chemical advertises that it makes active pharmaceutical ingredients. But Mr. Gu said he would export them only to countries with lower standards than China, or if "we can earn really good profits."

A Trail of Steroids

Just days before the Milan trade show, United States officials made an announcement that brought home the global reach and attendant dangers of China's expanding chemical industry. The officials disclosed that they had dismantled a 27-state underground network for steroids and human growth hormone, arresting 124 people in "Operation Raw Deal."

The supply trail almost always led to China. Thirty-seven companies there supplied virtually all of the bulk chemicals, federal officials said.

Of the 37 suspect companies, all but one unnamed by the American authorities, The Times identified eight. Records show that six are uncertified chemical companies, including Hunan Steroid, which marketed its products at the Milan convention.

“Just want to see the old customers and develop the new market,” said Sun Xueqin, a deputy export manager for Hunan Steroid. Ms. Sun said the company sold raw pharmaceutical ingredients in Europe and America and more advanced pharmaceutical ingredients in India, among other places.

Later, another Hunan official, Huang Zili, said the company did not sell to the United States, and declined to comment on the government’s contention that Hunan was a supplier of bodybuilding drugs. Hunan has not been charged with any crime.

As serious as the accusations are in Operation Raw Deal, health experts say they believe that counterfeit drugs, particularly those sold on the Internet, pose a greater threat to a broader segment of the American public.

“The facts are irrefutable,” Mr. Theriault, the former Pfizer official, told Congress. “The importation of counterfeit, infringing, misbranded and unapproved pharmaceutical products in the United States is increasing exponentially.” Pfizer makes Viagra, one of the drugs most often counterfeited.

Finding uncertified companies feeding the market is not difficult. Orient Pacific International, the Milan registrant whose owner did not show up, advertised that it makes and exports pharmaceutical ingredients to “worldwide famous medical companies.” The owner, Mr. Xu, is accused of selling counterfeit medicine to treat ailments like cancer, mental illness and heart disease, according to United States Immigration and Customs Enforcement, or I.C.E.

Mr. Xu shipped drugs to an Internet pharmacy, investigators say. But he also penetrated the highly regulated supply chain of legitimate distributors in Europe, said David A. Faulconer, a customs official. Acting on tips from large drug companies, federal officials devised a plan to stop him from doing the same in the United States.

Posing as a buyer, an investigator for the immigration and customs agency met Mr. Xu in Bangkok on March 6. Mr. Xu gave him “detailed suggestions for transshipment and smuggling techniques to evade United States Customs detection,” federal records show.

After investigators bought multiple shipments of counterfeit drugs, Mr. Xu traveled to Houston “to consummate an agreement for widespread distribution of his counterfeit products in the

United States,” according to an affidavit filed in federal court. Federal agents arrested Mr. Xu, who has pleaded not guilty.

Another company exhibiting in Milan, Honor International Pharmtech, was also the subject of a customs investigation. In January, agents seized 3,041 fake Viagra pills sent by the company to a DHL shipping hub in Wilmington, Ohio, according to customs.

The shipment, disguised as grape seed extract, was destined for an Internet pharmacy in Central America, said agents who requested anonymity because the investigation continues.

“We do make grape seed extract,” the company’s managing director, Nie An, said in a telephone interview. He denied shipping counterfeit Viagra, but he acknowledged other indiscretions: making false advertising claims, using another company’s import-export license and creating a fake corporate name.

“We don’t really have a factory,” Mr. Nie said, even though he advertised that he did. Honor International is just a trading company, he said, adding, “As a trading company, saying you can manufacture attracts business. It was fake advertising.”

The Times found several other companies posing as manufacturers, thereby obscuring a drug’s provenance. In a recent joint statement, chemical associations in the United States and Europe cautioned that globalization has led to a rise in complexity in supply chains, “increasing the potential for contamination, mislabeling or substitution.”

Pharmaceutical ingredients can pass through three or four trading companies, none of which check their quality. The ultimate manufacturer may not realize the ingredients came from an uncertified chemical company.

Mr. Nie, for example, said he markets Viagra’s main ingredient, sildenafil, through a partnership with a chemical company in a distant region that he has never visited. “We met them at a trade fair,” he said. “This company didn’t even have a booth at the fair. They were standing outside the entrance to the exhibition center, and they handed us a flier with a menu of their products.”

He said he was trying to reach the factory, which has no Web site, to fill a Croatian company’s order.

“Our main markets are in Latin America — Brazil, Argentina, Uruguay,” he said. “A little in Canada, a little in the United States. In Europe, we export to Germany, Russia, Italy.”

But Mr. Nie faces an uncertain future. He said that Chinese investigators had recently visited his office, and that they knew about the seizure in Ohio.

Viagra is hardly the only drug that companies try to copy. The French drug maker Sanofi-Aventis grew weary of watching other companies sell knockoffs of its new diet drug, Acomplia, and alerted French authorities that three Chinese companies were marketing their own version of the product at the 2006 pharmaceutical ingredient trade show, held in Paris. Six Chinese company officials were arrested.

One of those arrested in Paris was Jin Lijie, managing director of the Wuxi Hexia Chemical Company. Still, Wuxi Hexia showed up in Milan in 2007 selling a line of pharmaceutical ingredients.

Its representatives declined to be interviewed in Milan, or at its offices in the boomtown of Wuxi. "We are all young college graduates and we are still learning about the market," said an employee named Du Yanqun.

Factories on the Yangtze

A good place to find companies selling uncertified drug ingredients is Changzhou in the Yangtze delta, where the raw materials for chemical production are readily available and easily transported by canals and roads.

Several factories there sent representatives to Milan, including the Changzhou Kangrui Chemical Company. It makes pharmaceutical ingredients in an old converted steel plant. "I'm afraid it will leave you with a bad impression," said Zhou Ladi, a sales representative, as she gave a tour. She said Kangrui Chemical hopes to move into a new plant by early 2009.

"As long as we don't export products that are under patent in other countries, the government encourages us to export," she said.

To help find customers overseas, smaller factories enlist the services of people like Bian Jingya, export manager for a trading company called the Changzhou Wejia Chemical Company.

Ms. Bian said chemical companies are involved in all phases of drug manufacturing, including making finished products. Some, she said, "are under patent in other countries."

Ms. Bian, who was also in Milan, said the government should spell out more clearly what companies may and may not do. "If you want to be regulated, they will regulate you," she said. "If you don't want to be regulated, they don't."

The Chinese drug agency does not oversee the making of pharmaceutical raw materials, called intermediates, which are the building blocks for active pharmaceutical ingredients. "It is unrealistic for us to certify all factories that make intermediates and regulate them like medicine products," said Ms. Yan, the agency official. But if companies make active ingredients, a more refined product, then they must be regulated by drug authorities, she said.

When The Times pointed out that many uncertified chemical companies openly advertise active ingredients, Ms. Yan said that was illegal. "If there are in fact chemical companies that are making drugs without certification then this is very serious," she said. "These companies are not qualified to make medicine. They make chemicals."

Wang Siqing, managing director of the Changzhou Yabang Pharmaceutical Company, estimated that uncertified chemical companies make half the active pharmaceutical ingredients sold in China. "The stuff produced by chemical plants is clearly counterfeit medicine, but they aren't investigating," Mr. Wang said in an interview at his office. "This has been happening in a regulatory void." He added that most chemical company exports go to unregulated markets in Africa or South America. "That's not to say these products don't enter the United States through these other countries," he said.

To find out how well American consumers are being protected from unsafe imported drugs, investigators from the House Energy and Commerce Committee recently accompanied F.D.A. officials on inspections of drug plants in China and India.

In a letter to the F.D.A. commissioner, the committee said that the agency was unable to provide such basic information as the number of firms exporting to the United States, and that overseas F.D.A. inspectors lacked necessary logistical support. A House hearing on F.D.A. oversight of foreign drug manufacturers is scheduled for Thursday.

"China alone has more than 700 firms making drug products for the U.S., yet the F.D.A. has resources to conduct only about 20 inspections a year in China," said Representative John D. Dingell, the Michigan Democrat who is the chairman of the House Energy and Commerce Committee. The F.D.A. said it would answer the committee's questions at the hearing.

Poisonings in Haiti

United States officials learned of problems with China's chemical companies in the mid-1990s while investigating the fatal poisonings in Haiti. Chinese authorities took no action against the uncertified chemical company that made the poison, diethylene glycol, or the giant state-owned trader, Sinochem International Chemicals, that exported it.

A decade later another state-owned trading company, CNSC Fortune Way, exported the diethylene glycol — also from an uncertified chemical company — that ended up in the deadly Panamanian cold medicine in 2006.

Chinese officials have known for years that uncertified chemical companies are producing active pharmaceutical ingredients. In 2004 the Chinese drug authority's newspaper cited complaints that some licensed companies "affiliate" with unlicensed ones to hide their illegal purchases, while others buy only a token amount from certified suppliers to pass inspection. "The impact of chemical products on the bulk pharmaceutical market hints at a much larger problem: a huge hole in drug safety," the drug agency publication stated.

Since the Panama poisonings, China is considering ways to corral the chemical industry. At Panama's request, Michael O. Leavitt, the secretary of health and human services, has pressed the Chinese government to step up regulation of chemical companies selling pharmaceutical ingredients.

American and Chinese health officials held their first high-level meeting in May, and hope to sign a memorandum of agreement in December. "The Chinese have finally come to the realization that their regulatory system needs repair," said William Steiger, director of international affairs for Mr. Leavitt's agency. But meaningful change will be difficult. Chinese authorities may not have enough investigators to weed out the many small chemical companies that are making drug ingredients.

And efforts to close the regulatory gap must overcome one particularly thorny issue: some uncertified companies accused of selling counterfeit drugs are owned by the government itself.

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